K001256

MAY 2 4 2000

510(k) Summary
For Control Plasma N

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name: Donna A. Wolf
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P. O. Box 6101
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Preparation Date: April 17, 2000

Device Name / Classification: Control Plasma N
Quality control material, assayed, Class II (864.5425)

Predicate Device: Control Plasma N (K924403)

Device Description: Control Plasma N is a lyophilized, assayed control prepared from pooled human plasma, stabilized with HEPES buffer solution. It is intended to monitor and evaluate the precision and accuracy of coagulation and fibrinolysis tests in the normal range.

Device Intended Use: Control Plasma N is an assayed control for the following parameters in the normal range: Prothrombin time (PT), Activated partial thromboplastin time (aPTT), Thrombin time (TT), Batroxobin time, Fibrinogen, Coagulation factors II, V, VII, VIII (VIII:C, vWf:RCo), IX, X, XI, XII and XIII**, Inhibitors: Antithrombin III, Protein C, Protein S**, α 2-antiplasmin, C1-inhibitor**, Plasminogen, ProC APC, and Lupus anticoagulants.
** Not available in the U.S.

Comparison to Predicate Device:

	Control Plasma N (modified)	Control Plasma N (K924403)
Intended Use	Assayed control	Assayed control
Analytes	PT, aPTT, TT, Batroxobin time, Fibrinogen, Coagulation factors II, V, VII, VIII, IX, X, XI, XII, XIII*, Antithrombin III, Protein C, Protein S*, α-2 antiplasmin, C1-inhibitor*, Plasminogen, ProC APC, Lupus anticoagulants. * not available in the U.S	PT, aPTT, TT, Batroxobin time, Fibrinogen, Coagulation factors II, V, VII, VIII, IX, X, XI, XII, XIII*, Antithrombin III, Protein C,Pprotein S*, α-2 antiplasmin, C1-inhibitor*, Plasminogen, ProC APC. * not available in the U.S
Matrix	Stabilized reagent from human plasma	Stabilized reagent from human plasma
Form	Lyophilized	Lyophilized
Volume	1 ml per vial	1 ml per vial

Comments on Substantial Equivalence: Both the Control Plasma N (modified) and Control Plasma N (current) are similar products. Both products are intended for use as a control of coagulation and fibrinolysis tests in the normal range.

Conclusion: The Control Plasma N (modified) is substantially equivalent to the Control Plasma N (current) based on the comparison summarized above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 2 4 2000

Ms. Donna A. Wolf
Regulatory Affairs Specialist, Biology
Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714

Re: K001256
Trade Name: Control Plasma N
Regulatory Class: II
Product Code: GIZ
Dated: April 17, 2000
Received: April 19, 2000

Dear Ms. Wolf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K001256
Device Name: Control Plasma N

Indications for Use:

Control Plasma N is an assayed control for the following parameters in the normal range:

1. Prothrombin time (PT)
2. Activated partial thromboplastin time (aPTT)
3. Thrombin time (TT)*
4. Batroxobin time*
5. Fibrinogen
6. Coagulation factors II, V, VII, VIII (VIII:C, vWf:RCo), IX, X, XI, XII and XIII**
7. Inhibitors: Antithrombin III, protein C, protein S**, α 2-antiplasmin, C1-inhibitor**
8. Plasminogen
9. ProC APC
10. Lupus anticoagulants

* Not for BFT II
** Not available in the U.S.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ (Per 21CFR801.109) OR Over-The-Counter-Use ____ (Optional Format 1-2-96)

Peter E. Madsen
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001256